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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,981	03/30/2004	Tae-Woong Koo	INTEL1490 (P18518)	8675
28213	7590	07/05/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP			DO, PENSEE T	
4365 EXECUTIVE DRIVE			ART UNIT	
SUITE 1100			PAPER NUMBER	
SAN DIEGO, CA 92121-2133			1641	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/814,981

Applicant(s)

KOO ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/1/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting in line 3 "associating.." because it is unclear of how the first specific binding pair member associates with the SERS active particle or substrate, i.e. adsorption, covalent binding, or close in proximity etc.?

Claim 18 recites the limitation "the surface-enhanced Raman scattering label is deoxyadenosine monophosphate" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. The specification is silent on deoxyadenosine monophosphate or using such compound as a SERS-active label.

Claim 22, 26 and 31 are indefinite because step d) in claims 22 and 26 and step c) in claim 31 recites that "detecting a difference in a surface-enhanced Raman scattering signal generated by the antibody/ immobilized first specific binding pair member". The antibody/immobilized first specific binding pair member does not contain or is not bound to any label or means that generates a surface-enhanced Raman scattering signal". Thus, how would an antibody or an immobilized first specific binding pair member generate any signal if it's not attached to a label or means to generate a signal?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, 13-17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarcha et al. (US 5,376,556).

Tarcha teaches a method, composition, device and kit for the determination of the presence or amount of an analyte by monitoring an analyte-mediated ligand binding even in a test mixture which contains the analyte to be assayed, a specific binding member, a Raman-active label and a particulate having a surface for inducing a surface-enhanced Raman light scattering. The differences in the detected surface-enhanced Raman scattering spectra are dependent upon the amount of analyte present in the test mixture. (col. 5, line 60-col. 6, line 9; line 65-col. 7, line 6). Regarding claims 3 and 20, Tarcha teaches that the specific binding member is attached to the SERS-active surface by direct adsorption, attachment through intervening molecule or a linker arm, covalently attached to the specific binding member or by the covalent attachment of the specific binding member to a coating on the SERS-active surface directly or through a linker arm or by intercalation of the distal portion of a linker arm into the enhancing surface. (see col. 14, lines 23-33). The conjugate of the SERS-active surface and the specific binding member is contacted with the complementary specific binding

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member (or analyte) and detecting a difference in a surface-enhanced Raman scattering signal of the conjugate before contacting the with the complementary binding member and after contacting with the complementary binding member thereby detecting the binding of the binding members. The difference in the surface-enhanced Raman scattering signal is a decrease in the signal (The samples which had been pre-exposed to free biotin (analyte or second specific binding member) showed weaker signals than those which did not come in contact with biotin-- see example 18). The Raman active particle or substrate is a metal particle such as gold, silver or copper. (see col. 10, lines 3-11). Regarding claim 11, Tarcha teaches that an enhancer such as salt can be added into the mixture. (see col. 9, lines 50-55). The first and second specific binding member is a protein, antibody molecule or fragment thereof, receptor and ligand, nucleic acid molecules. (see col. 33-54). The first specific binding pair member is bound to a surface-enhanced Raman scattering label. (see col. 14, lines 34-60). With respect to claim 9 and 10, Tarcha teaches in example 4, col. 18, lines 31-50, that the DNB solution display the SERS enhancement when absorbed to the silver film. A DNB solution in the absence of an island film gave a very weak Raman spectrum. With regards to claim 8, Tarcha teaches in example 6, fig. 5 that SERS signal is measured at different concentration of target analyte and there is an increase in intensity as the concentration increases. The first specific binding member is a antibody or fragment thereof. Regarding claim 7, the present specification teaches on page 7, [0027], that "SERS signal generated by the first binding pair member is reduced when a second specific binding pair member quenches the SERS signal of the first specific binding pair

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member. This quenching of the SERS signal can be the result of dissociation of the first specific binding pair member from the SERS active substrate upon binding of the second specific binding pair member to the first member". Since Tarcha teaches that when the second binding pair member binds to the first binding pair member, the SERS signal is reduced. Thus, it is inherent that the result of such reduction in SERS signal in Tarcha is the result of dissociation of the first specific binding pair member from the SERS active substrate/particle upon binding of the second binding pair member to the first member.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarcha et al. (US 5,376,556) in view of Fray (US 4,904,356).

Tarcha has been discussed above.

However, Tarcha fails to teach the chemical salt is lithium chloride.

Fray teaches using lithium chloride salt to as a salt of a metal surface to be refined. Such salt when saturating the metal surface allows the metal ions to move through freely. (see col. 1, lines 27-40).

It would have been obvious to one of ordinary skills in the art to use lithium chloride as taught by Fray as an enhancer for the metal surface in the assay mixture as

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in the method of Tarcha since Tarcha teaches using an enhancer such as a salt. Since this salt is used for refining metal surface, advantageously when it is used as an enhancer, it keeps the metal ions on the metal surface intact or prevents the metal ions on the metal surface from being wear off.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarcha et al. (US 5,376,556) in view of Gole et al. (US 6,589,883).

Tarcha has been discussed above.

However, Tarcha fails to teach the SERS active substrate is a porous silicon substrate comprising impregnated metals.

Gole teaches metalizing substrates such as porous silicon for use in Raman scattering detection. (see col. 1, line 60-col. 2, line 3; col. 3, lines 1-3; lines 34-42).

Since Tarcha teaches that the surface of the Raman active substrate can be made of metal of silica (see col. 11, lines 52-55), it would have been obvious to one of ordinary skills in the art to use porous silicon substrate coated with metals as a Raman-active substrate as taught in Gole because high-surface area substrates such as porous silicon display a visible photoluminescence upon excitation with a variety of visible and ultraviolet light sources.

Claims 5, 22-28, 30, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarcha et al. (US 5,376,556) in view of Maine et al. (US 6,221,619).

Tarcha has been discussed above.

However, Tarcha fails to teach immobilizing the first specific binding pair member/antibody on an immobilizing substrate.

Maine teaches different assay formats comprising attaching antibody/antigen to a solid phase such as porous, non-porous materials, latex particles, magnetic particles, microparticles, beads, membranes, microtiter wells, and plastic tubes. One of the antibody/antigen reagents used in an immunoassay is attached to a signal-generating compound or label. This signal-generating compound is in itself detectable or may be reacted with one or more additional compounds to generate a detectable product. Detection systems is Raman spectroscopy. (see col. 9, line 52-col. 10, line 20).

It would have been obvious to one of ordinary skills in the art to immobilize the antibody/antigen to a solid phase such as magnetic particles, beads, etc. as taught by Maine before attaching to a signal generating compound such as colloidal metal particles in the method of Tarcha because immobilization of the antibody/binder/antigen to a solid support before attaching the antibody/binder to colloidal metal particles for a surface enhanced scattering signal detection can capture the analyte and detect at the same time without using a second capture antibody.

Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Tarcha et al. (US 5,376,556) in view of Maine et al. (US 6,221,619) as applied to claim 22-28, 30-34 above, and further in view of Fray (US 4,904,356).

Tarcha and Maine have been discussed above.

However, Tarcha and Maine fail to teach the first specific binding pair member is adsorbed on the metal particle in the presence of lithium chloride.



Fray teaches using lithium chloride salt to as a salt of a metal surface to be refined. Such salt when saturating the metal surface allows the metal ions to move through freely. (see col. 1, lines 27-40).

It would have been obvious to one of ordinary skills in the art to use lithium chloride as taught by Fray as an enhancer for the metal surface in the assay mixture as in the combined method of Tarcha and Maine since Tarcha teaches using an enhancer such as a salt. Since this salt is used for refining metal surface, advantageously when it is used as an enhancer, it keeps the metal ions on the metal surface intact or prevents the metal ions on the metal surface from being wear off.

### ***Conclusion***

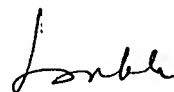
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
June 23, 2005



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